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10/520,140

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Michael Brines

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20583

7590

03/24/2010

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EXAMINER

WOODWARD, CHERIE MICHELLE

ART UNIT

PAPER NUMBER

1647

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                       |                                      |  |
|------------------------------|---------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/520,140  | <b>Applicant(s)</b><br>BRINES ET AL. |  |
|                              | <b>Examiner</b><br>CHERIE M. WOODWARD | <b>Art Unit</b><br>1647              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-10, 12-16, 24-46 and 54-59 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-10, 12-16, 24-46 and 54-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/18/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Formal Matters***

1. Applicant's response and amendments filed 12/18/2009 are acknowledged and entered. Claims 1-5, 8-10, 12-16, 24-46, and 53-55 are pending. Claims 6-7, 11, 17-23, and 47-52 have been cancelled by Applicant. New claims 56-59 have been added. Claims 1-5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 8-10, 12-16, 24-46, and 53-59 are under examination.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 12/18/2009 has been considered. A signed copy of the IDS is attached hereto. English language abstracts in foreign language documents have been considered. However, the foreign language portions of the references have not been considered. The IDS has been considered to the extent possible given the length and substantial number of references submitted to the examiner, who only has a limited time to consider such a vast number of references. Additionally, there is no statement as to materiality or the cumulative nature of any of the references in the 19 pages of IDS documents. Applicant is reminded of the requirements of 37 CFR 1.56 and *Li Second Family Limited Partnership v. Toshiba Corp.*, 56 USPQ2d 1681 (Fed. Cir. 2000); accord *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.* 487 F.3d 897, 913. (Fed.Cir.2007). Applicants submissions have been made without any statement as to the relevance, cumulative nature, or materiality of the references or any indication of the relevance or materiality of any the art cited therein. These references and copending applications have been considered to the extent possible given the issues set forth above and the examiner's limited amount of time for examination.

### ***Response to Arguments***

#### ***Claim Objections/Rejections Withdrawn***

3. The rejection of claims 8-10, 13-16, 43-46, and 54-55 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn.

4. The rejection of claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn.

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5. The rejection of claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn.

6. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn.

7. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn.

8. The rejection of claims 8-10, 12-16, 24-46, and 53-55 under 35 U.S.C. 103(a) as being unpatentable over Escary, WO 02/085940 (31 October 2002, benefit to 21 December 2001), Satake et al. (Biochimica et Biophysica Acta. 1990;1038:125-129) (previously cited of record), and Brines et al., (PNAS USA, 2000 Sept 12; 97(19):10526-10531) (previously cited of record), is withdrawn.

***Claim Objections/Rejections Maintained***

***Obviousness-Type Double Patenting Rejections***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided

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the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 8-10, 12-16, 25, 43, 54, and 55 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,531,121 (11 March 2003, benefit to 29 December 2000). The Terminal Disclaimer filed 12/18/2009 was DISAPPROVED.

The words "legal title" does not include common ownership as to equitable title required to be included by 37 CFR 1.321 (c)(3) in the use of the words "commonly assigned." 37 CFR 1.321(c)(3) requires that a Terminal Disclaimer "[i]nclude a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting."

11. Claims 8, 15, 16, 28-31, 33, 34, 36, 39, 53, and 54 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 14, 16-21, 25, 28, 29, 61, 62, and 63 of copending Application No. 10/185,841 (now allowed) in view of Brines et al., (PNAS USA, 2000 Sept 12; 97(19):10526-10531) (previously cited of record). Because this copending application has been allowed, this rejection is no longer provisional. The Terminal Disclaimer filed 12/18/2009 was DISAPPROVED.

The words "legal title" does not include common ownership as to equitable title required to be included by 37 CFR 1.321 (c)(3) in the use of the words "commonly assigned." 37 CFR 1.321(c)(3) requires that a Terminal Disclaimer "[i]nclude a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting."

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12. Claims 8, 13-16, 31, 32, and 43 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35, 37, 38, 50-60 of copending Application No. 10/188,905. The Terminal Disclaimer filed 12/18/2009 was DISAPPROVED.

The words "legal title" does not include common ownership as to equitable title required to be included by 37 CFR 1.321 (c)(3) in the use of the words "commonly assigned." 37 CFR 1.321(c)(3) requires that a Terminal Disclaimer "[i]nclude a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting."

***New Objections/Rejections – Necessitated by Amendment***

***Claim Rejections - 35 USC § 112, Second Paragraph***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 8-10, 12-16, 24-46, and 54-59 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Applicant has attempted to amend the specification (via a sequence listing) to incorporate essential material set forth in paragraph 5 of the specification, as originally filed, by adding SEQ ID NO:5, which is the well-known amino acid sequence of EPO. Applicant submitted the amended sequence listing on 4/14/2009. However, because the 4/14/2009 was non-responsive to the previous Office Action, the sequence listing was not entered. If Applicant desires to incorporate SEQ ID NO: 5 as essential material, the sequence listing must be resubmitted in order to be considered and entered. Because SEQ ID NO: 5 is claimed, but is not presently part of the specification, Applicant has failed to set forth the subject matter which Applicant regards as their invention.

***New Obviousness-Type Double Patenting Rejections***

***Necessitated by Amendment and Necessitated by the IDS filed of 12/18/2009***

15. Claims 8 and 56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 39 and 41 (to be issued as claims 1 and 2) of copending allowed Application No. 10/573,905. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to the same or overlapping subject matter. Adhesion formation is directly or indirectly related to an inflammatory pathology.

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16. Claims 8 and 56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 27 of copending Application No. 11/631,458. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to the same or overlapping subject matter. Many diseases of excitable tissue, broadly including muscle and neural tissue, are directly or indirectly related to an inflammatory pathology, including, but not limited to myositis and multiple sclerosis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 56 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10 and 14 of copending Application No. 11/880,275. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to the same or overlapping subject matter. Stroke and ischemia are directly or indirectly related to an inflammatory pathology.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 56 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10 and 11 of copending Application No. 11/881,759. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to the same or overlapping subject matter. Diseases of the central nervous system or peripheral nervous system, including multiple sclerosis, are directly or indirectly related to an inflammatory pathology.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Advisory Notice***

19. This application contains claims drawn to an invention nonelected with traverse in the reply filed on 12/19/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

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***Conclusion***

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 12/18/2009 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/  
Primary Examiner, Art Unit 1647